

REMARKS

Applicants respectfully request the Examiner to reconsider the present application in view of the foregoing amendments to the claims and the following remarks.

Status of the Claims

Claims 1-15 are currently pending in the present application. The Office Action is non-final. Claims 1, 7, 9-10, 12 and 13 have been amended without prejudice or disclaimer. Claims 2-6 and 8 have been cancelled without prejudice or disclaimer. Claim 15 is new. No new matter has been added by way of amendment, because each amendment further defines and clarifies each of the structures of the present invention and is supported by the present specification.

Based upon the above considerations, entry of the present amendments is respectfully requested.

In view of the following remarks, Applicants respectfully requests that the Examiner withdraw all rejections and allow the currently pending claims.

Rejections Under 35 U.S.C §112, Second Paragraph, Indefiniteness

Claims 12-14 stand rejected under 35 USC §112, second paragraph as being indefinite. The Examiner states that the term “alleviation” is confusing and that correction is required. Applicants respectfully traverse.

Although Applicants do not agree that the claims are indefinite, to expedite prosecution, claims 12 and 13 have been amended herein, without prejudice or disclaimer, per the Examiner’s request to recite, in part, “the treatment or lessening the effects of a disease or disorder...”

Therefore, in light of the amendments of claims 12 and 13, reconsideration and withdrawal of the indefiniteness rejection of claims 12-14, is respectfully requested.

Rejection Under 35 U.S.C §112, First Paragraph, Enablement

Claims 12-14 stand rejected under 35 USC §112, first paragraph as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The Examiner asserts that the instantly claimed invention is highly unpredictable since one skilled in the art would recognize that in regards to the therapeutic effects, whether or not the compounds of formula of claim 1 would be useful for treating or preventing disorder diseases is efficacious. The Examiner also asserts that the Applicants provides no guidance for how compounds of formula (I) could treat or prevent any and all known diseases and that there are no working examples in the instant application showing that the instant compounds can treat or prevent disorder diseases. nor are there any examples of the disease being either treated or prevented by the compounds of formula (I). Applicants respectful traverse.

The Examiner is reminded that, "As long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. 112 is satisfied." (*See, In re Fisher*, 427 F.2d 833, 839, 166 U.S.P.Q. 18, 24 (CCPA 1970)). The Examiner assertion that the Applicants' lack of disclosure as not providing even a single example is inconsistent with the substantial body of work disclosed by the present specification, including formulation of pharmaceutical compositions (at pages 16-19), preparation of the compounds (at page 15 and pages 20-33), biological activity (page 15 which cites in vitro assays from WO 97/30997; see pages 10-15 WO 97/30997) and methods of therapy (at page 20).

The Examiner appears to be requiring Applicants to provide examples in the specification to prove enablement support. However, we respectfully remind the Examiner that as recently decided in *Falko-Gunter Falkner v. Inglis*, Fed. Cir. 2006, 05-1324, citing *LizardTech, Inc. v. Earth Resource Mapping, PTY, Inc.*, 424 F.3d 1336, 1345 (Fed. Cir. 2005), a “claim will not be invalidated on section 112 grounds simply because the embodiments of the specification do not contain examples explicitly covering the full scope of the claim language.” Thus, rejection of the presently claimed invention based solely on the lack of examples is improper.

Applicants submit that at least there is adequate enablement support in the specification for the scope within claims 12 to 14.

Thus, for at least these reasons, Applicants believe that the Examiner has failed to set forth a *prima facie* case of non-enablement. (*See, In re Oetiker*, 24 U.S.P.Q.2d 1443 (Fed. Cir. 1992), stating, “[i]f the examination at the initial stage does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of the patent.”).

Reconsideration and withdrawal of the enablement rejection of claims 12-14 are respectfully requested.

Claims 12-14 stand rejected under 35 USC §112, first paragraph as failing to comply with the enablement requirement. The Examiner asserts that the specification, while enabling for treating specific diseases, does not reasonably provide enablement for preventing diseases. Applicants respectfully traverse.

Applicants have amended claims 12 and 13, without prejudice or disclaimer, to remove the word “preventing” from the claims as per the Examiner’s suggestion.

Applicants respectfully request reconsideration and subsequent withdrawal of the present rejection.

Rejections Under 35 U.S.C §102(b), Anticipation

Claims 1, 3-4, 6 and 10 stand rejected under 35 USC § 102(b) as anticipated by Ananthan et al., Bioorganic & Medicinal chemistry letters, 2002, Vol. 12, pages 2225-2228 (hereinafter "Ananthan et al."). The Examiner asserts that Ananthan et al. disclosed a compound on page 2227, Table 1, compound 4a, that is claimed within the present invention.

Applicants respectfully traverse. Compound 4a has a 2-phenyl substituted quinazolinyl moiety. However, such a phenyl substitution of the heteroaryl group is not within the scope of the pending claims. Therefore, these claims are not anticipated by Ananthan et al.

Claims 1, 3, 6, and 10-11 stand rejected under 35 U.S.C. § 102(b) as anticipated by Yasuhiro et al. European Patent EP 1213289 (hereinafter "Yasuhiro et al."). The Examiner asserts that Yasuhiro et al. discloses several compounds (see Office Action item 7, page 8-9) which are from the STN search that are claimed within the present invention. Applicants respectfully traverse.

Based upon review of the structures within the Office Action it does not appear that these compounds are described within the claims. The compounds from Yasuhiro et al. are heavily substituted 8-azabicyclo[3.2.1]oct-3-yl-amino azetidin derivatives. However, in the pending

claims, R^b cannot represent an azetidin group - only an aromatic ring system. Therefore, these claims are not anticipated by Yasuhiro et al.

Claims 1, 3-4, 6-7, and 10-11 stand rejected under 35 U.S.C. § 102(b) as anticipated by Saltarelli et al., WO 2000/071107 (hereinafter "Saltarelli et al."). The Examiner asserts that Saltarelli et al. discloses a claimed compound, 6-[4-[(8-methyl-8-azabicyclo[3.2.1]oct-3-yl)oxy]-1-naphthalenyl] 2-Pyridinamine, which is from the STN search and claimed within the present invention.

Applicants respectfully traverse. In Saltarelli et al. the compound cited by Examiner has a naphthyl group substituted with an amino-pyridin. However, such a pyridin substitution of the naphthyl group is not within the scope of the presently pending claims. Therefore, these claims are not anticipated by Saltarelli et al.

Claims 1, 3-4, 6-7, and 10-11 are rejected under 35 U.S.C. § 102(b) as anticipated by Bakken et al., Journal of medicinal chemistry, 2000, Vol. 43, pages 4534-4541. (hereinafter "Bakken et al.") The Examiner asserts that Bakken et al. discloses 5H-Benzo[4,5]cyclohepta[1,2-b]pyridine, 5-[[[(3-endo)-8-methyl-azabicyclo[3.2.1]oct-3y-yl)oxy] which is from the STN search and claimed within the present invention.

Applicants respectfully traverse. Based upon review of the structure within the Office Action it does not appear that this compound is described within the claims. As to the Bakken et al. reference, the compound cited by Examiner is not within the scope of the presently pending

claims as the 5H-benzo[4,5]cyclohepta[1,2-b]pyridine moiety is not an aromatic ring system. Therefore, these claims are not anticipated by Bakken et al.

Claims 1, 3, 5, 6, 8, and 10-11 stand rejected under 35 U.S.C. § 102(b) as anticipated by Chenard, U.S. Patent No. 5,710,168 (hereinafter "Chenard"). The Examiner asserts that Chenard discloses two compounds which are from the STN search and claimed within the present invention.

Applicants respectfully traverse. Based upon review of the structure within the Office Action, the compounds from Chenard that were cited by the Examiner have a hydroxyphenyl-propanol-yl substituent in the 8-position of the 8-azabicyclo[3.2.1]octane skeleton and are not within the scope of the presently pending claims. The R^a substituent cannot represent a phenyl-substituted hydroxyalkyl. Therefore, these claims are not anticipated by Chenard.

Claims 1,3, 6, and 9-11 stand rejected under 35 U.S.C. § 102(b) as anticipated by Himmelsbach et al., WO 97/32881 (hereinafter "Himmelsbach et al."). The Examiner asserts that Himmelsbach et al. discloses a compound which is from the STN search and claimed within the present invention.

Applicants respectfully traverse. Based upon review of the structure it does not appear that the compound is described within the claims. The compound within Himmelsbach et al. that the Examiner asserts is within the claims is incorrect, as the heteroaryl group in the position of R^b cannot be substituted by a (substituted) phenylamino. Applicants believe, therefore, these claims are not anticipated by Himmelsbach et al.

In light of the above arguments, Applicants respectfully request reconsideration and subsequent withdrawal of all the anticipatory rejections cited above.

In view of the above amendment, applicant believes the pending application is in condition for allowance.

CONCLUSION

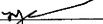
In view of the above remarks, it is believed that claims are allowable.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Paul D. Pyla, Reg. No. 59,228 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.14; particularly, extension of time fees

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Respectfully submitted,

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